

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

TAMMY MUZICHUCK, Individually,
as Administratrix of the
Estate of Bruce Muzichuck,
and on behalf of her minor
child, Hannah Muzichuck,

Plaintiff,

v. // CIVIL ACTION NO. 1:07CV16
(Judge Keeley)

FOREST LABORATORIES, INC. and
FOREST PHARMACEUTICALS, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFF'S
MOTION [DKT. NO. 36], CAPTIONED AS A MOTION FOR JUDGMENT
ON THE PLEADINGS, BUT CONSTRUED AS A MOTION TO STRIKE

The plaintiff in this case, Tammy Muzichuck ("Mrs. Muzichuck"), has sued the defendants (1) in her individual capacity, (2) in her capacity as the administratrix of the estate of her deceased husband, Bruce Muzichuck ("Mr. Muzichuck"), and (3) on behalf of her minor child, Hannah Muzichuck. Pending before the Court is Mrs. Muzichuck's motion, which is incorrectly captioned as a motion for judgment on the pleadings. (Dkt. No. 36). The motion, nevertheless, seeks to strike an affirmative defense raised in the answer of one of the defendants, Forest Laboratories, Inc. ("Forest"). (Dkt. No. 37). Therefore, the Court construes the

motion as a motion to strike under Fed. R. Civ. P. 12(f),¹ and, for the following reasons, **GRANTS** the motion.

I. BACKGROUND

In 2006, Mrs. Muzichuck filed a complaint in the Circuit Court of Marion County, West Virginia, alleging that Forest had manufactured an anti-depressant drug, known as "Lexapro,"² that caused Mr. Muzichuck to commit suicide by gunshot in 2004. Prior to shooting himself, Mr. Muzichuck recently had been prescribed an increased dosage of Lexapro by his physician. The complaint alleges claims of negligent failure to warn, strict liability, fraud, wrongful death, breach of implied warranty, and punitive damages. After removing the case to this Court, Forest filed an answer, asserting several affirmative defenses, including the "learned intermediary doctrine."³ (Dkt. No. 37 at 12).

¹ A Rule 12(f) motion to strike is more appropriate than a Rule 12(c) motion for judgment on the pleadings "where a plaintiff challenges only some of the defenses raised in a defendant's pleading." Haley Paint Co. v. E.I. Du Pont De Nemours & Co., 279 F.R.D. 331, 335 (D. Md. 2012); see also 5C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1380 (3d ed. 2004) ("A motion to strike under Federal Rule 12(f) . . . is the primary procedure for objecting to an insufficient defense.").

² According to the complaint, Lexapro is in a class of drugs known as selective serotonin reuptake inhibitors, which also includes Prozac, Paxil, and Zoloft. (Dkt. No. 1-1 at 6-7).

³ "'The learned intermediary doctrine provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products.'" West Virginia ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 902 (W. Va. 2007) (quoting In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002)). Under the doctrine, a drug manufacturer is excused from warning every customer if it properly warns prescribing physicians of the drug's dangers. Id. at 901 n.1.

Due to a flurry of similar products liability actions against Forest, in March 2007, the Judicial Panel on Multidistrict Litigation ("JPML") consolidated the cases for pre-trial proceedings in the United States District Court for the Eastern District of Missouri. After the case had spent several years in the transferee court, in August 2013, the JPML remanded it to this Court for further proceedings.

Mrs. Muzichuck filed her motion to strike on November 22, 2013. In it, she argues that, based on the decision of the West Virginia Supreme Court of Appeals in West Virginia ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007), the learned intermediary doctrine "does not exist under West Virginia substantive law." (Dkt. No. 36-1 at 1). In response, Forest argues that Karl's holding is limited to cases that present evidence of direct-to-consumer advertising, and that the learned intermediary doctrine does not violate West Virginia's public policy.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(f) allows a district court, either "on its own" or "on motion made by a party," to strike from any pleading "an insufficient defense." Although Rule 12(f) motions to strike are generally viewed with disfavor, "a defense that might confuse the issues in the case and would not, under the facts alleged, constitute a valid defense to the action can and should be deleted." Waste Mgmt. Holdings, Inc. v. Gilmore, 252

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F.3d 316, 347 (4th Cir. 2001) (internal citation and quotation marks omitted). Moreover, "[a] court may strike a defense that is clearly insufficient as a matter of law." Hanzlik v. Birach, No. 1:09CV221, 2009 WL 2147845, at *3 (E.D. Va. July 14, 2009).

III. DISCUSSION

The only question presented is whether the learned intermediary doctrine is cognizable where there is no evidence that the defendant-drug manufacturer marketed its prescription drug directly to consumers. A thorough discussion, however, requires an analysis of the decision of the West Virginia Supreme Court of Appeals in Karl, a review of several post-Karl decisions, and an examination of the West Virginia legislature's 2011 enactment in W. Va. Code § 55-8-16.

A. Karl

When West Virginia's highest court rendered its decision in West Virginia ex rel. Johnson & Johnson Corp. v. Karl in 2007, the issue of "whether [the learned intermediary doctrine] should be adopted into the common law of West Virginia" was "one of first impression." 647 S.E.2d at 902. That said, prior to 2007, the federal district courts within West Virginia had speculated that the state would adopt the doctrine. See, e.g., Ashworth v. Albers

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Med., Inc., 395 F. Supp. 2d 395, 407 (S.D.W. Va. 2005); Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 338 (N.D.W. Va. 1995). Their speculation proved erroneous, however, when, in Karl, the West Virginia Supreme Court of Appeals declined to validate those opinions. 647 S.E. 2d at 913 n.18.

In Karl, the respondent-patient had been prescribed Propulsid® by her physician for treatment of digestive issues. Id. at 901. After three days of use, she suddenly died. Id. Her estate filed a products liability and medical malpractice action against the drug's manufacturer and the prescribing physician. Id. The manufacturer filed a motion for summary judgment on the basis that, under the learned intermediary doctrine, it had satisfied its duty to warn the physician of the drug's potential dangers. Id. The circuit court denied the manufacturer's motion. Id. Subsequently, the manufacturer filed a motion in limine to exclude any evidence of its failure to warn the decedent. Id. Again, the circuit court denied the motion. Id. Thereafter, the manufacturer filed a writ of prohibition asking the West Virginia Supreme Court of Appeals to prohibit enforcement of the circuit court's order denying its motion in limine, and to adopt the learned intermediary doctrine. Id.

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In denying the manufacturer's writ, the court stated as follows:

Given the plethora of exceptions to the learned intermediary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized. . . . Furthermore, we believe that if drug manufacturers are able to adequately provide warnings to consumers under the numerous exceptions to the learned intermediary doctrine, then they should experience no substantial impediment to providing adequate warnings to consumers in general. . . . Finally, because it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products. . . . West Virginia physicians naturally have duties and responsibilities regarding their role in providing prescription medicines to consumers. It would be unreasonable not to require the manufacturers to accept similar responsibilities. Based upon the foregoing, we now hold that, under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule.

Id. at 913-14.

B. Post-Karl Decisions

As Forest correctly points out, the Karl court relied, in significant part, on the proliferation of direct-to-consumer advertising in declining to adopt the learned intermediary

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doctrine. See Karl, 647 S.E.2d at 909. However, Forest's assertion that "Karl did not kill the learned intermediary doctrine in West Virginia[] because of the specific direct to consumer marketing context" is incorrect. (Dkt. No. 38 at 7). In an effort to exhume the doctrine from its judicially-dug grave, Forest cites two post-Karl cases - one published, the other unpublished - from the United States District Court for the Southern District of West Virginia.

In the first of these cases, the estate of a decedent-employee sued the chemical manufacturer-employer and one of its chemical suppliers after the decedent died from exposure to vinyl chloride monomer ("VCM"). Roney v. Gencorp, 654 F. Supp. 2d 501, 502 (S.D.W. Va. 2009) (Chambers, J.). In defense of the plaintiff's failure to warn claim, the chemical supplier asserted the "sophisticated user" defense.⁴ Id. The district court observed that, contrary to the learned intermediary doctrine, which "the

⁴ Although related to the learned intermediary doctrine, the sophisticated user defense differs significantly. "In its purest form, the sophisticated user defense discourages direct warning by allowing manufacturers to rely on purchasing claims to relay warnings to end users. The defense relieves manufacturers of liability for injuries caused by intermediate purchasers' failure to warn the next purchaser in line. Initial manufacturers are thus not liable for such breaks in the chain of warnings." Kenneth M. Willner, Failures to Warn and the Sophisticated User Defense, 74 Va. L. Rev. 579, 580 (1988).

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[Karl] court decided not to adopt," the sophisticated user defense "has not been explicitly adopted or rejected in West Virginia." Id. at 502, 504.

In offering its best judgment as to whether West Virginia courts would adopt or reject the sophisticated user defense, the district court looked closely at the reasoning in Karl. Id. at 504-05. It observed that "[c]entral to the reasoning was the fact that drug companies now engage in extensive direct-to-consumer advertising," and it described Karl as "extremely context specific." Id. The court further noted Karl's recognition that "through such advertising pharmaceutical companies had gained direct access to patients, a relationship starkly different than that which had existed when the doctrine was developed - when patients received drug information exclusively through their doctors." Id. at 505.

It went on to distinguish the facts of its case by analogizing the relationship of worker to employer in the chemicals industry to the relationship of patient to doctor in the days when the learned intermediary doctrine was developed. Id. In other words, chemical plant workers "were insulated from the manufacturer of the chemicals they used, much as the patient used to be insulated from

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the drug manufacturer.” Id. Thus, the court was unpersuaded that Karl portended West Virginia’s rejection of the sophisticated user defense. Id.

The second of the two cases relied on by Forest is Vagenos v. Alza Corp., No. 1:09CV1523, 2010 WL 2944683 (S.D.W. Va. July 23, 2010) (Faber, J.). In Vagenos, the estate of a decedent whose death allegedly was due to her use of a fentanyl patch sued the manufacturer, the distributor, and the retailer of the patch. Id. at *1. The retailer successfully moved to dismiss the case based on the learned intermediary doctrine. Id. In granting the motion to dismiss, the district court reasoned that, “[g]iven the [direct-to-consumer advertising] rationale underpinning the [Karl] decision and the fact that the Karl court did not discuss the doctrine in the context of a pharmacist’s duty to warn, . . . the court predicts that the West Virginia Supreme Court of Appeals would find that the learned intermediary doctrine shields [the retailer-pharmacy] from liability on the failure to warn claim.” Id. at *5.

Relying on the rationale of Roney and Vagenos, Forest urges that, “[a]bsent evidence of direct to consumer marketing of Lexapro to the end user prior to decedent’s death on December 5, 2004, the learned intermediary doctrine should remain a viable affirmative

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defense under West Virginia law.” (Dkt. No. 38 at 9). Both cases, however, differ from the instant case, and the Court is unpersuaded that they support the conclusion Karl does not apply here.

In Karl, the West Virginia Supreme Court of Appeals did not distinguish between cases that present evidence of direct-to-consumer advertising and those that do not. Indeed, as Forest argues, the dissent in Karl highlighted the majority's failure to draw such a distinction:

What the majority overlooks by emphasizing the direct marketing of drugs to consumers is that the doctrine may still serve a useful purpose for prescription drugs that are not heavily marketed and in those circumstances where a physician's expertise is relied upon to make the all-important selection of which particular drug(s) to prescribe; to interpret contraindicative information; and to interpret the myriad of warning-related information distributed by a pharmaceutical manufacturer.

Karl, 647 S.E.2d at 914-15 (Albright, J., dissenting). Whether Karl's failure in this regard was prudent or not has no bearing on the Court's application of the majority's holding. Moreover, despite Forest's reliance on Roney and Vagenos, neither case recognized the distinction in the context of a prescription drug manufacturer's assertion of the learned intermediary doctrine.

In Roney, Judge Chambers declined to extend the presumption of direct-to-consumer advertising to the chemical manufacturing

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industry because workers in that industry "were insulated from the manufacturers of the chemicals they used." 654 F. Supp. 2d at 505. Instead, he recognized that Karl's reasoning "is not applicable to a scenario outside of the prescription pharmaceutical context." Id.

Vagenos is distinguishable from Karl to the extent that the party asserting the learned intermediary doctrine in that case was a retailer-pharmacy. In contrast, here, as in Karl, the party asserting the defense is the pharmaceutical manufacturer. And, as acknowledged by Judge Faber, "the Karl court abolished the doctrine as to manufactures [sic] only." Vagenos, 2010 WL 2944683, at *5.

Despite their holdings, Roney and Vagenos both explicitly recognize that Karl prohibits defendant-prescription drug manufacturers from asserting the learned intermediary doctrine. Thus, the Court rejects Forest's argument that a plaintiff must proffer evidence of direct-to-consumer advertising by a drug manufacturer in order for Karl to apply. Rather, because the instant case involves the assertion of the learned intermediary doctrine by a defendant-prescription drug manufacturer, the holding of Karl applies squarely to prohibit the defense.

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C. Public Policy

Like Roney and Vagenos, several other cases, including two from this Court, have noted the unavailability of the learned intermediary doctrine for prescription drug manufacturers in West Virginia. Notably, these cases have concluded that the bar of the doctrine is grounded in public policy, in addition to direct-to-consumer advertising. See Locklear v. Mylan, Inc., No. 1:10CV164, 2011 WL 3296635, at *5 (N.D.W. Va. Aug. 1, 2011) ("[T]he West Virginia Supreme Court of Appeals has declared that the learned intermediary doctrine violates the state's public policy."); Vitaoe v. Mylan Pharm., Inc., 696 F. Supp. 2d 599, 609 (N.D.W. Va. 2010) ("[T]he public policy of West Virginia bars the application of Louisiana's learned intermediary doctrine."); Woodcock v. Mylan, Inc., 661 F. Supp. 2d 602, 607 (S.D.W. Va. 2009) ("The analysis in Karl reveals that West Virginia's rejection of the learned-intermediary doctrine is grounded in public policy.").

Forest argues extensively that these cases were wrongly decided, and that public policy was not a basis for the Karl decision.⁵ Forest argues that this conclusion is evidenced by

⁵ The Court need not reach the issue of whether Karl was decided on public policy grounds in order to render its decision in this case.

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recent legislation, entitled "Choice of Law in Pharmaceutical Product Liability Actions," which provides as follows:

(a) It is public policy of this state that, in determining the law applicable to a product liability claim brought by a nonresident of this state against the manufacturer or distributor of a prescription drug for failure to warn, the duty to warn shall be governed solely by the product liability law of the place of injury ("lex loci delicti").

(b) This section shall be applicable prospectively to all civil actions commenced on or after July 1, 2011.

§ 55-8-16. According to Forest, the statute has "gutted" the Karl decision. (Dkt. No. 38 at 12).

Far from gutting Karl, § 55-8-16 simply provides a choice of law rule with respect to prescription drug products liability actions. If in such cases the plaintiff is not a West Virginia resident, and the case was filed on or after July 1, 2011, pursuant to the statute the court shall apply the product liability law of the state where the injury occurred. Aside from any effect it might have on Karl, § 55-8-16 does not come close to applying to the facts at issue here. Not only is Mrs. Muzichuck a West Virginia resident, but she filed this action nearly five years prior to the effective date of the statute. Moreover, even if the statute were applicable, because Mr. Muzichuck's suicide occurred

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in West Virginia, this state's products liability law, i.e., Karl, would apply.

IV. CONCLUSION

Despite Forest's urging to the contrary, Karl remains the applicable substantive law regarding the learned intermediary doctrine in West Virginia. That case forthrightly rejects the doctrine as a cognizable defense to be asserted by prescription drug manufacturers. Furthermore, § 55-8-16 does not abrogate Karl's holding, nor does it apply to the case at bar. Therefore, for the reasons discussed, the Court **GRANTS** Mrs. Muzichuck's motion to strike the learned intermediary doctrine from Forest's answer.

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Memorandum Opinion and Order to counsel of record.

DATED: July 15, 2014.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE